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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,574	11/17/2003	Mutsuya Kitazawa	30293-64	4721

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EXAMINER	
NAGPAUL, JYOTI	
ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 08/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/715,574	KITAZAWA, MUTSUYA	
	Examiner	Art Unit	
	Jyoti Nagpaul	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-32 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1-24** are rejected under 35 U.S.C. 102(b) as being anticipated by Venooker (US 5573046).

Venooker teaches a valve assembly for fluid delivery. Venooker teaches a fluidic coupling component which provides fluidic connection and an analytical instrument. (See Col.1 , lines 16-17) The assembly comprises of a first cylindrical ring/coupling means (54) to mate in fluid communication with the tissue processor. Venooker further discloses a connector fitting/locking assembly (130) for attaching the coupler in fluid communication with the analytical instrument/tissue processor. Venooker recites, "the connector fitting 130 is adapted to be operatively connected to the complementary manifold fitting of aspirating means which forms part of an analytical instrument." (See Col. 9, Lines 23-26) Venooker recites, "The connector fitting 130 is inserted into the cavity 150 of the manifold fitting 55 by aligning the tab 137 with the slot 162 and the tab 139 with the slot 164 and pushing the end surface 129 toward the access surface 154. The coupling means 54 is then rotated clockwise to a predetermined position as viewed in FIG. 34. The bevels 143 and 149 engage the inner surfaces 159 and 161, respectively and function as cam surfaces to guide the tabs 137 and 139 between each

of the first and second projections 158 and 160, respectively, and the access surface 154. The bevels 143 and 149 are biased against the surfaces 159 and 161, respectively, by the elastomeric sealing ring 133." (See Col. 11, Lines 8-21) A second cylindrical ring (50) in fluid communication with the first cylindrical ring (54) and configured to mate with the fluid container (40). (See Figure 5) The coupler is configured to provide bidirectional fluid communication between the fluid container and the tissue processor. Venooker recites, "a fluid delivery system in which a coupling component is removably connected at one end to the analytical instrument and the other end to the container and a fluid seal is created at both ends of the coupling component while allowing liquid to be aspirated from the container to the instrument and air to be drawn into the container from outside of the container to replace the aspirated liquid." (See Col. 2, Lines 27-35) As shown in Figure 5, the first and second cylindrical rings are separated by a wall. The device further comprises a fluid conduit (144) (See Figure 10) disposed within the first (54) and second cylindrical (50) rings and passing through the wall, thereby providing fluid communication from the fluid container to the tissue processor/analytical instrument. A retention cylindrical ring (89) disposed within the second cylindrical ring (50). (See Figure 10) As shown in Figure 4, the retention cylindrical ring (89) is disposed around the fluid conduit forming a cylindrical gap (82) between the fluid conduit and retention cylindrical ring. The fluid container includes tubing (61) dimension to fit within the cylindrical gap (82). (See Figure 5) As shown in Figure 5, the first cylindrical ring (54) includes a diameter that is less than a diameter of the second cylindrical ring (50). Venooker teaches a outer groove/ventilation aperture

(148) which extends beyond the cap assembly to create an air or gas passageways between the chamber 80 to a point outside of the bottle cap.

3. **Claims 26 and 29-32** are rejected under 35 U.S.C. 102(b) as being anticipated by Clark.

Clark discloses method and apparatus for an automated biological reaction system. The method comprises of providing a fluid container assembly including a fluid container having a neck, a coupler/spring attached to the neck and a cap attached to the coupler. Clark recites, "the caps 454, 434 can be spring-biased to the closed position, with the opening pins 472 remaining in contact with the tab lever 454(b), 433, respectively, subsequent to the opening operation as described above to maintain the caps 454, 434 in an open position to allow aspiration of reagents from the reagent container 441 with a pipette probe. Once the pipette probe has been withdrawn from the reagent container 441, the opening pins 472 move in an upward direction away from tabs 454(b), 433 to allow the caps 454, 434 to return to their evaporatively sealed closed positions." (See 176) Then placing the fluid container assembly adjacent to the tissue processor and providing fluid communication between the fluid container and the tissue processor. Clark recites, "pipette probe transfer mechanism can either be located at a remote location or station removed from the cap actuator station 464, thereby requiring movement of a reagent pack 30' to such pipette probe transfer mechanism for access of reagents in a reagent container 441 by the pipette probe." (See 177) The system further positions the fluid container assembly adjacent an appropriate locking assembly. Clark recites, "a reagent pack can be mounted or

otherwise positioned on a non-concentric or linear conveyor system, whereby such non-concentric system reciprocates with a reagent pack to facilitate the opening and closing of a capped-closure as described herein." (See 177) Clark further comprises a locking assembly/cap closure assembly the step of displacing a portion of a locking assembly relative to coupler/spring includes the step of pulling a handle/lever. Clark recites, "the heads of the cap actuator 474 partially lowered to drag along the top of the cap 454 and overcome the force of the internal spring, thereby returning the cap 454 to a partially closed position or the soft seal position with the stopper 454(a) in the opening of the closure 452." (See 174) Clark discloses presently known techniques for container closure systems such as septum caps.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. **Claim 25** is rejected under 35 U.S.C. 103(a) as being unpatentable over Venooker in view of Clark.

Refer above for the teaching of Venooker.

Venooker fails to teach the locking assembly and coupler are color coordinated.

Refer below for the teaching of Clark.

Clark also teaches each sample container includes an identifying number or bar code.

It is known in the art to include different type of markings, numbers, color codes, or bar codes. It would have been obvious to one of the ordinary skill in this art at the time of the invention by applicant to modify the system of Venooker such that the locking assembly and coupler are color coordinated in order to facilitate the user as to what type of reagent is used at which test sample.

7. **Claim 27-28** are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark.

Refer above for the teachings of Clark.

Clark fails to teach the step of positioning the fluid container assembly adjacent an appropriate locking assembly includes the step of matching the color of the container with the color of a locking assembly.

Clark also teaches each sample container includes an identifying number or bar code.

It is known in the art to include different type of markings, numbers, color codes, or bar codes. It would have been obvious to one of the ordinary skill in this art at the

time of the invention by applicant to modify the system of Clark such that an appropriate locking assembly includes the step of matching the color of the container with the color of a locking assembly in order to facilitate the user as to what type of reagent was used at which test sample in order to decrease contamination as well.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jyoti Nagpaul whose telephone number is 571-272-1273. The examiner can normally be reached on Monday thru Friday (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JN

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